Rhodia

August 20, 2008

MRH
313686

US Environmental Protection Agency
OPPT Document Control Office (Mail Code 7407)
1200 Pennsylvania Ave, NW
EPA East Room 6428
Washington, DC 20460
ATTN: Section 8(e) Coordinator

Contain NO CBI

RE: Notification of Substantial Risk: AG-RHO FKC 1000[1]

Dear Sir or Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), Rhodia Inc. (Rhodia) is submitting the following information:

Rhodia is having conducted a dose range-finding study for a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening test (OECD 422) using rats treated with doses of 0, 50, 150 and 300 mg/kg/day by oral gavage. These groups are identified in the report as Groups 1, 2, 3, and 4, respectively. At the end of the study, findings were recorded involving macroscopic and microscopic changes in several organs and tissues.

The treatment-related macroscopic findings recorded by the laboratory were: thickened forestomach mucosa in one male of Group 3 and in almost all males and females of Group 4, and several crateriform retractions of the forestomach in one Group 3 and in two Group 4 females. In addition, several black-brown foci were observed in the forestomach of one female of Group 2. All these gross lesions could be correlated with microscopic findings recorded in the forestomach (see below).

One lung of a female of Group 4 did not collapse at necropsy. This finding correlated microscopically with a chronic-active peribronchial/peribronchiolar inflammation with fibrosis and was considered to be due to aspiration of the test item, not due to toxicity.

Microscopically, in the kidneys, urothelial and collecting duct hyperplasia occurred in animals of Groups 3 and 4, as did granular casts and an increased incidence and severity of tubular basophilia and mononuclear cell infiltrates. Minimal granular casts were found also in one Group 3 male. Urothelial hyperplasia in the urinary bladder was recorded in one male of group 4 and in females of groups 3 and 4.

In the stomach, various degrees of ulceration/erosion, squamous hyperplasia, hyperkeratosis, parakeratosis, pustules, submucosal inflammation and edema were recorded in the forestomach of animals of Groups 2, 3 and 4. Mucosal necrosis as well as submucosal edema and inflammation were found randomly distributed in the glandular stomach of Group 3 and 4 animals.

[1] This material is identified as a mixture of: Dodecanaminium, N-(carboxymethyl)-N,N-dimethyl-, hydroxide, inner salt (CAS# 683-10-3, 20%), Tetradecanaminium, N-(carboxymethyl)-N,N-dimethyl-, hydroxide, inner salt (CAS# 2601-33-4, 7%), Potassium chloride (CAS# 7447-40-7, 8%), and water (CAS# 7732-18-5)

CN 7500 Cranbury, New Jersey 08512
Direct Telephone: 215-369-9734, Direct Fax: 609-860-5927
E-mail: Judith.Kranetz@us.rhodia.com

In addition, there was an increased incidence and severity of extramedullary hematopoiesis in the adrenal glands (cortices) of females of Group 4.

Increased granulopoiesis was observed in the bone marrow of females of Groups 2-4 and in males of Groups 3 and 4, with the highest incidence and severity recorded in Group 4 animals.

The findings recorded in kidneys, urinary bladder and stomach were considered to be of adverse character. The adverse findings were considered to be so because they impaired the function of the respective organs. The findings recorded in adrenal glands and bone marrow were considered to be not of adverse nature, since they were of minimal severity and they did not impair the organ function.

Based on the fact that some findings were observed in Group 2, the lowest dose tested, a NOAEL could not be established for the study.

Although Rhodia Inc. does not believe that this substance would present an unreasonable hazard to workers or to the public when properly used in its intended applications, we believe these results may meet the EPA's reporting criteria for TSCA Section 8(e). Further, these data may meet the reporting criteria of FIFRA Section 6(a)(2), as this study will be used to support the use of this product as an inert ingredient in pesticide formulations, and the information contained in this letter may be considered to be new. Because submissions under FIFRA Section 6(a)2 require EPA registered numbers of active ingredients or end-use formulations and this product does not have such a number, we could not submit under FIFRA Section 6(a)2.

Rhodia has previously submitted an "FYI Notification" to EPA on this material, based on the results of a dose range-finding study used to set doses for the study reported above.

The preliminary results reported in this letter were first reviewed by Rhodia on July 25, 2008. Rhodia asserts that none of the information contained within this notice constitutes confidential business information. Should you have any questions, or require any further information, please call (215) 369-9734. Thank you.

Very truly yours,
RHODIA INC.

Judith L. Kranetz
Manager, Regulatory Compliance & Product Stewardship

JLK/
Atts
Ref: 08-0024L.doc
Fed Ex A/B 8642-0318-8112

Cc:
Document Processing Desk – 6(a)(2) – Fed Ex A/B #8642-0318-8101
Office of Pesticide Programs
Room 266A
Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202